

**510(k) SUMMARY**  
**(as required by 807.92(c))**

**Regulatory Correspondent:** AJW Technology Consultants Inc  
445 Apollo Beach Blvd  
Apollo Beach, FL 33572  
John O'Brien  
[jobrien@ajwtech.com](mailto:jobrien@ajwtech.com)  
813-645-2855 x101  
813-645-2856

**Submitter of 510(k):** Infinium Medical  
12151 62<sup>nd</sup> Street North #5  
Largo, FL 33773  
Suleyman Bilgutay  
[sales@infiniummedical.com](mailto:sales@infiniummedical.com)

**Date of Summary:** June 8, 2013

**Trade/Proprietary Name:** Omni Series Patient Monitors

**Common Name:** Patient Physiological Monitor (without Arrhythmia Detection or Alarms)

**Classification Name:** Monitor, physiological, patient (without Arrhythmia detection or alarms)

**Device Class:** II

**Device Panel:** Cardiovascular

**Product Code:** MWI

**Subsequent Product Codes:**

| Regulation Number | Description                            | Product Code | Applicable Monitor |
|-------------------|--|--------------|--------------------|
| 870.2340          | Electrocardiograph                     | DPS          | All                |
| 870.1130          | Noninvasive Blood Pressure Measurement | DXN          | All                |
| 870.2700          | Oximeter                               | DQA          | All                |
| 868.2375          | Breathing frequency                    | BZQ          | All                |

|          |  |     |                         |
|----------|--|-----|-------------------------|
|          | monitor  |     |                         |
| 880.2910 | Clinical Electronic Thermometer                    | FLL | All                     |
| 870.1110 | Blood Pressure Computer                            | DSK | OMNI, OMNI II, OMNI III |
| 870.1425 | Programmable diagnostic computer                   | DQK | All                     |
| 870.1435 | Single-function, preprogrammed diagnostic computer | DXG | OMNI II, OMNI III       |
| 868.1400 | Carbon dioxide gas analyzer                        | CCK | All                     |

### **Intended Use:**

#### **OMNI**

The purpose and function of the OMNI patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3, 5 or 12 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO<sub>2</sub>
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO<sub>2</sub>
- IBP
- Anesthetic agents

The target population is for adult, neonate and pediatric patients.

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

OMNI II

The purpose and function of the OMNI II patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3, 5 or 12 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO<sub>2</sub>
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO<sub>2</sub>
- Cardiac Output
- IBP
- Anesthetic agents

The target population is for adult, neonate and pediatric patients with the exception of:

- Cardiac Output for which the target population is adult only.

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

OMNI III

The purpose and function of the OMNI III patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3, 5 or 12 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO<sub>2</sub>
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO<sub>2</sub>
- Cardiac Output
- IBP
- Anesthetic agents

The target population is for adult, neonate and pediatric patients with the exception of:

- Cardiac Output for which the target population is adult only.

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

### OMNI Express

The purpose and function of the OMNI Express patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3 to 5 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO<sub>2</sub>
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO<sub>2</sub>
- Anesthetic agents

The target population is for adult, neonate and pediatric patients.

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

### **Device Description:**

#### OMNI

The OMNI monitor is a comprehensive monitoring system with four, six or eight traces compiling, and processing, analyzing and displaying data from up to eight different patient parameters. It integrates parameter measuring modules, display and recorder in one device, featuring in compactness, lightweight and portability. Built-in battery facilitates transportation of patient.

The OMNI monitor can be powered by an internal battery pack that provides 1 hour of monitoring from fully charged batteries. The batteries are continuously recharged when AC power is connected to the monitor.

#### OMNI II

The OMNI II monitor is a comprehensive monitoring system with four, six or eight traces compiling, and processing, analyzing and displaying data from up to eight different patient parameters. It integrates parameter measuring modules, display and recorder in one device, featuring in compactness, lightweight and portability. Built-in battery facilitates transportation of patient.

The OMNI II monitor can be powered by an internal battery pack that provides 1 hour of monitoring from fully charged batteries. The batteries are continuously recharged when AC power is connected to the monitor.

**OMNI III**

The OMNI III monitor is a comprehensive monitoring system with eight traces compiling, and processing, analyzing and displaying data from up to six different patient parameters. It integrates parameter measuring modules, display and recorder in one device, featuring in compactness, lightweight and portability. Built-in battery facilitates transportation of patient.

The OMNI III can be powered by an internal battery pack that provides 1 hour of monitoring from fully charged batteries. The batteries are continuously recharged when AC power is connected to the monitor.

**OMNI Express**

The OMNI EXPRESS monitor is a comprehensive monitoring system with two or three traces compiling, and processing, analyzing and displaying data from up to eight different patient parameters. It integrates parameter measuring modules, display and recorder in one device, featuring in compactness, lightweight and portability. Built-in battery facilitates transportation of patient.

The OMNI EXPRESS monitor can be powered by an internal battery pack that provides 2 hours of monitoring from fully charged batteries. The batteries are continuously recharged when AC power is connected to the monitor.

**Substantial Equivalence:**

The OMNI patent monitor is substantial equivalent in intended use and similar technological characteristics of IBP, CO<sub>2</sub>, Anesthetic Agents, and 12 Lead ECG to the Datascope Corp. Spectrum™ Monitor under K062098.

The OMNI II and OMNI III are substantially equivalent to the Datascope Corp. Spectrum™ Monitor under K062098 in intended use and similar technological characteristics of IBP, CO<sub>2</sub>, Anesthetic Agents, 12 Lead ECG and Cardiac output .

The OMNI Express is substantially equivalent to the Datascope Corp. Spectrum™ Monitor under K062098 as it pertains to CO<sub>2</sub> and Anesthetic Agents.

The OMNI Patient Monitors are substantially equivalent to the previously cleared OMNI Patient Monitors as it pertains to previously cleared technological characteristics and performance. A comparison of these technological characteristics is included in the submission.

| <b>Device</b>                      | <b>Clearance Number</b> | <b>Substantial Equivalence to</b>  |
|------------------------------------|-------------------------|--|
| Datascope Corp – Spectrum™ Monitor | K062098                 | Intended use and functions of IBP, CO <sub>2</sub> , Cardiac Output, Anesthetic Agents |
| OMNI Patient Monitor               | K112329                 | Intended use<br>Previously Cleared Technological Characteristics and Performance       |
| OMNI II Patient Monitor            | K103737                 | Intended use   |

|                              |          |  |
|------------------------------|----------|--|
|                              |          | Previously Cleared Technological Characteristics and Performance                 |
| OMNI III Patient Monitor     | K101052  | Intended use<br>Previously Cleared Technological Characteristics and Performance |
| OMNI Express Patient Monitor | K1037268 | Intended use<br>Previously Cleared Technological Characteristics and Performance |

**Rational for Substantial Equivalence:**

The testing completed in the previously cleared submissions along with the additional testing completed demonstrates that the OMNI Series Patient Monitors exhibit comparable mechanical and functional characteristics to the predicate devices in addition to being biocompatible acceptable. Based on those characteristics, the Infinium OMNI Patient Monitors are substantially equivalent to the predicate devices in safety and effectiveness in addition to being intended for the same uses.

**Summary of Non-Clinical Data:**

The OMNI series patient monitors underwent bench testing according to several different performance standards. Below is a chart of the different testing that was completed.

| Patient Monitor   | Performance Test | Standard of Compliance         |
|-------------------|------------------|--------------------------------|
| OMNI              | IBP              | BS EN 60601-2-34:2000          |
|                   | ECG              | ANSI/AAMI<br>EC13:2002/(R)2007 |
| OMNI II, OMNI III | IBP              | BS EN 60601-2-34:2000          |
|                   | ECG              | ANSI/AAMI<br>EC13:2002/(R)2007 |
|                   | Cardiac Output   | No Standard                    |

Based on the conclusions of each of these tests it is determined that the OMNI Patient Monitors are safe and effective.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

February 21, 2014

Infinium Medical  
c/o Mr. John O'Brien  
445 Apollo Beach Blvd  
Apollo Beach, FL 33572 US

Re: K132229  
Trade/Device Name: Omni Patient Monitors  
(Models: Omni, Omni II, Omni III and Omni Express)  
Regulation Number: 21 CFR 870.2340  
Regulation Name: Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)  
Regulatory Class: Class II  
Product Code: MWI  
Dated: January 13, 2014  
Received: January 16, 2014

Dear Mr. O'Brien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.



Page 2 - Mr. John O'Brien

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Owen P. Faris -S**

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: OMNI Patient Monitor

The purpose and function of the OMNI patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3, 5 or 12 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO<sub>2</sub>
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO<sub>2</sub>
- IBP
- Anesthetic agents

The target population is for adult, neonate and pediatric patients:

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

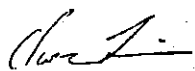
AND/OR

Over-The-Counter Use  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



Digitally signed by  
Owen P. Faris -S  
Date: 2014.02.21  
14:03:26 -05'00'

Page 1 of 1

Indications for Use

510(k) Number (if known):

Device Name: OMNI II Patient Monitor

The purpose and function of the OMNI II patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3, 5 or 12 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO<sub>2</sub>
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO<sub>2</sub>
- Cardiac Output
- IBP
- Anesthetic agents

The target population is for adult, neonate and pediatric patients with the exception of:

- Cardiac Output for which the target population is adult only.

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

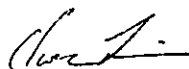
AND/OR

Over-The-Counter Use  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



Digitally signed by  
Owen P. Faris -5  
Date: 2014.02.21  
14:03:43 -05'00'

Page 1 of 1

Indications for Use

510(k) Number (if known):

Device Name: OMNI III Patient Monitor

The purpose and function of the OMNI III patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3, 5 or 12 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO<sub>2</sub>
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO<sub>2</sub>
- Cardiac Output
- IBP
- Anesthetic agents

The target population is for adult, neonate and pediatric patients with the exception of:

- Cardiac Output for which the target population is adult only.

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

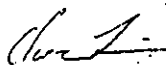
AND/OR

Over-The-Counter Use  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



Digitally signed by  
Owen P. Farls -5  
Date: 2014.02.21  
14:04:01 -05'00'

Page 1 of 1

Indications for Use

510(k) Number (if known):

Device Name: OMNI Express Patient Monitor

The purpose and function of the OMNI Express patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3 to 5 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO<sub>2</sub>
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO<sub>2</sub>
- Anesthetic agents

The target population is for adult, neonate and pediatric patients:

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

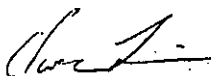
AND/OR

Over-The-Counter Use  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



Digitally signed by  
Owen P. Faris -S  
Date: 2014.02.21  
14:04:19 -05'00'

Page 1 of 1